



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,880	12/19/2001	Eugene Bell	TSS-018DV	6914
26161	7590	02/24/2004		
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			EXAMINER ORTIZ, ANGELA Y	
			ART UNIT 1732	PAPER NUMBER

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/024,880	Applicant(s) BELL, EUGENE	
	Examiner Angela Ortiz	Art Unit 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-22 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-22 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/19/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-22, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al., USP 6,475,239 in view of Vacanti et al., USP 5,855,610.

The cited primary reference substantially teaches the basic claimed method of forming a heart valve including providing a mold which replicates the structure of a heart valve including leaflets as claimed, filling the mold with biocompatible material, processing the material and forming a valve body. See col. 2, lines 55-67; col. 4, lines 8-52.

The cited primary reference does not teach the claimed scaffold, collagen and freeze drying the scaffold.

Art Unit: 1732

The added secondary reference teaches as conventional the feature of a scaffold as claimed for making flexible, strong connective tissues, including collagen materials for the claimed purposes and using the scaffold in the making of heart valves. See col. 3, lines 60-67; col. 4, lines 1-65; col. 5, lines 25-35, 55-67; col. 7, lines 40-65; col. 8, lines 1-25.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the scaffold and collagen materials as set forth in the added reference, when making the heart valve of the primary reference, for making a heart valve having improved, flexible, strong connective tissues.

Note that the freeze-drying is well known for preserving tissues and their properties and would have been obvious to include for preserving the formed valve.

With respect to claims 13-17, note that the added reference teaches biopolymer scaffolds, collagen materials and signaling molecules. See col. 4, lines 1-65.

With respect to claims 19-22, note that seeding is disclosed at col. 7, lines 20-55.

With respect to claim 18, note that the primary reference sets forth the use of a sewing ring, and teaches provision of places for sutures. It would have been obvious to include the step of sewing for assembling the edges as desired.

Conclusion

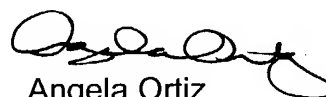
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. USP's 6179872; 5804178; 5770193; 6146892; 6673285.

Art Unit: 1732

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Ortiz whose telephone number is 571-272-1206. The examiner can normally be reached on Monday-Thursday 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 571-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Angela Ortiz
Primary Examiner
Art Unit 1732

ao